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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,504

11/19/2003

Gordon H. Epstein

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10/28/2008

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EXAMINER

RYCKMAN, MELISSA K

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

10/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/718,504

Applicant(s)

EPSTEIN ET AL.

Examiner

MELISSA RYCKMAN

Art Unit

3773

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19, 21-26 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 21-26 and 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

This office action is in response to claims filed 7/16/08.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19, 21-26, 28-30, 31, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latson et al. (US 5861003) and further in view of Khairkahan et al. (US 2002/0111647).

Latson teaches an expansible device for use in a body lumen or tract, the device comprising:

- a tubular member (12) having a lumen, a proximal end, and a distal end
- a first expansible member (distal portion of 6) disposed on the distal end of the tubular member, the first expansible member having a contracted configuration and an expanded configuration, wherein the first expansible member consists essentially of a single wire (9) that can be retracted into the lumen of the tubular member (Figs. 4 and 5) to shift the single wire

from a helical expanded configuration to a straightened contracted configuration

- a first deformable membrane at least partially disposed over the first expansible member in the expanded configuration (distal portion of 6)
- a second expansible member (5) disposed proximal to the first expansible member and on the distal end of the tubular member, the second expansible member having a contracted configuration and an expanded configuration comprising a cylindrical shape (Fig. 4, 5 is a cylinder)
- wherein the first deformable membrane has a spherical shape when the first expansible member is in the expanded configuration (Fig. 6)
- a predetermined volume of air contained within the tubular member inflates the second expansible member so as to provide at least one of radial or axial expansion (inherently a predetermined volume of air will fill the second expansible member)
- the second expansible member (5) comprises a coil or spring of wire (9)
- a second deformable membrane (5) at least partially disposed over the second expansible member in the expanded configuration (fig. 6)
- ribs on a surface of the second deformable membrane (col. 4, ll. 36,37)
- the second expansible member has a length in a range from about 0.1 inch to about 2.0 inches (Fig. 5)
- a reference stop (7) disposed between the first deformable membrane and the distal end of the tubular member (Fig. 5)

- the first and second expansible members are deployed sequentially (Fig. 4-5)

Latson does not specify wherein the first deformable membrane has a spherical shape when the first expansible member is in the expanded configuration and the second expansible member has a cylindrical shape in the expanded configuration. Latson does however say the bag is preferably disc shaped, however the term preferably means there are other options for the shape of the expansible member (Latson, col. 3, ll. 6). Khairkhahan teaches a spherical shape when expanded (Figs. – 10). It would have been obvious to one of ordinary skill in the art to use the shape of Khairkhahan with the device of Latson as the spherical shape may be preferable in different applications, as the front face would be rounded instead of flat, making the entry of the device into a certain body part smoother. The sphere of Khairkhahan is structurally stonger than the disc of Latson, because the stress concentration is evenly distributed in a sphere.

Regarding Claim 23, Latson fails to disclose the diameter of the coil wire. Khairkhahan teaches a device for occluding an opening, wherein the second expansible member is of a diameter .19 inches. It would have been an obvious matter of design choice to disclose the diameter of the coil and wire as being within the disclosed range since it appears that the device of Latson performs the task of closing a hole in tissue equally well as that of the disclosed application, and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

The combination of Latson and Khairkhahan teaches the claimed invention, and further teaches wherein wherein the first and second expansible members are deployed sequentially, but fails to teach wherein the first and second expansible members are deployed simultaneously. It would have been an obvious matter of design choice to modify the method of Latson by simultaneously deploying the first and second expansible members, since the combination of Latson and Khairkhahan is capable of performing that function, and in paragraph 79 of the present application, applicant asserts that it is preferable to deploy the first and second members sequentially, and it appears that the method of the combination of Latson and Khairkhahan performs the task of sealing a puncture equally well as that of the present application.

Claims 19, 21, 29, 30 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latson and Khairkhahan as applied to claim 29 above, and further in view of Brennenman et al. (US 6071300).

Latson and Khairkhahan teach the claimed invention but do not teach the specified locations of the first and second expansible members, however Brennenman teaches the first expansible member is deployed against a blood vessel wall (fig. 1) and the second expansible member is deployed against a tissue tract (fig. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Latson and Khairkhahan in the location of Brennenman, as this is common and successful in the art.

Response to Arguments

Applicant's arguments filed 7/16/08 have been fully considered but they are not persuasive. The applicant generally argues:

- Latson fails to teach the geometries

The examiner agrees with the applicant, Latson fails to teach the geometries, however the geometries are taught by Khairkahan as described in the above rejection. Latson however does teach the second expandable member is a cylinder, as seen in several of the figures.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773